REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 59-131 are pending in this application and have all been rejected.

Claims 59-83 and 85-91 have been amended herein, and claim 84 has been canceled.

35 U.S.C. § 102 Rejections

The Examiner has maintained his rejections of claims 59-91 under 35 U.S.C. § 102(e) as being anticipated by Weidner et al. (International Patent Appl. Publ. No. WO 02/02509). The Examiner stated that, because the chemical structure of the oral solid dosage form of insulin taught by Weidner et al. is identical to the claimed invention, Weidner et al. inherently teaches the claimed functional limitations.

In the February 8, 2008 Response, Applicants traversed this rejection. Applicants argued that the fact that the dosage form achieves a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient as compared to an untreated diabetic patient is not inherently disclosed in Weidner et al. Applicants contended that there is not a reasonable expectation that the solid oral delivery capsule disclosed in Weidner et al. would necessarily meet the additional functional limitations as claimed, because the animal studies described in Weidner et al. were not performed on diabetic animals, and that the results of claim 59 obtained by Applicants after administration of the oral dosage form to diabetic human subjects would not necessarily have been recognized at the time of the prior art reference as being able to be obtained by the same dosage form used in the prior art as was administered to non-diabetic non-human animal subjects. Applicants also argued that Weidner et al. is not sufficiently described and enabled with respect to how that composition would perform when administered to diabetic

human subjects and that it would have required undue experimentation to determine how the Weidner et al. composition would perform when administered to diabetic human subjects in comparison to non-treated diabetic human subjects. The Examiner was not persuaded by these arguments.

Applicants further argued that, simply because Weidner et al. discloses the broad genus of the composition and the species of administration to non-diabetic animals, Weidner et al. still does not necessarily disclose the species of how that composition would perform when administered to diabetic human subjects in comparison to non-treated diabetic human subjects. Applicants contended that Weidner et al. merely invites further experimentation to find out how the described oral solid dosage form would perform when administered to diabetic human subjects in comparison to non-treated diabetic human subjects. The Examiner was not persuaded by this argument, stating that claims 59-91 are drawn to compositions, not methods, such that the fact that Weidner et al. is silent as to administration of the composition to diabetic humans is insufficient to overcome the rejection.

In response, Applicants have amended claims 59-83 and 85-91 (claim 84 has been canceled) so that they are now drawn to methods of treating diabetes in humans, not to compositions. As such, the fact that that Weidner et al. is silent as to administration of the composition to diabetic humans is sufficient to overcome the rejection. The method of treating humans claimed in claims 59-83 and 85-91 are certainly not anticipated by Weidner et al., since no administration to human is contemplated.

Applicants respectfully request that the Examiner withdraw this rejection of amended claims 59-83 and 85-91 under 35 U.S.C. § 102(e) as being anticipated by Weidner et al.

Double Patenting Rejections

Claims 92-131 were provisionally rejected for obviousness-type double patenting over claims 1-29, 33-38 and 40-59 of U.S. Patent Appl. No. 10/541,433.

Claims 59-131 were provisionally rejected for obviousness-type double patenting over claims 1-92 of U.S. Patent Appl. No. 11/072,941.

Claims 59-131 were provisionally rejected for obviousness-type double patenting over claims of U.S. Patent Appl. No. 11/204,778.

Applicants note that these rejections are provisional, as none of the cited applications has issued as a U.S. patent. In response, Applicants herewith submit Terminal Disclaimers to disclaim the term of any patent to be granted off this application beyond the term of any patent to be granted on any of the cited applications. Accordingly, in view of the Terminal Disclaimers, Applicants respectfully request that the Examiner withdraw these rejections.

Conclusion

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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